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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/431,607 11/01/99 HENDERSON

L 15280-169300

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TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO CA 94111-3834

EXAMINER

FOLEY, S

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/431,607

Applicant(s)

HENDERSON ET AL.

Examiner

Shanon A. Foley

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 22-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____

DETAILED ACTION

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). Application 08/379,420 is not listed on the first line of the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is drawn to a composition comprising an inactivated retrovirus that has been inactivated with nitric oxide and “derivatives containing the NO group”. The metes and bounds of what a “derivative” of a substance containing an NO group has not been defined and it cannot be discerned what any derivative containing an NO group would be. This is especially the case since the claim later describes that the compound is not a C-nitroso compound having the formula: R-C-NO. Also, all substances containing cupric ions or ferric ions and “complexes” have not been defined to a degree in which the metes and bounds can be immediately interpreted. This rejection affects all dependent claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1648

Claims 22-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 22 states that the compound that inactivates the retrovirus is not a C-nitroso compound having the formula: R-C-NO. No support for this negative limitation can be found in the specification. The courts have found that any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). This is a new matter rejection.

Claims 22-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to a composition comprising an inactivated retrovirus that has been inactivated with disulfides (R-S-S-R), maleimides with a specific formula, hydrazides with a specific formula, nitric oxide and derivatives thereof, and compounds containing cupric ions or ferric ions and complexes thereof. The specification does not teach a way for one of skill in the art to readily identify a range of compounds containing cupric ions or ferric ions, or NO derivatives, of a certain structure would still inactivate all retroviruses without undue experimentation. The compounds that merely contain cupric or ferric ions read on compounds with no defined structure, and the specification does not reasonably convey possession of these

Art Unit: 1648

undefined compounds. There is no specific written description that specifically identifies a range of structures to enable any compound containing cupric ions or ferric ions or NO derivatives that would immediately identify itself to one of skill in the art to practice the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-24, 26, and 27 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Ryser et al. (PNAS. May 1994. 91: 4559-4563).

The claims are drawn to a composition comprising an inactivated HIV that has been inactivated with 5,5'-dithiobis(2-nitrobenzoic acid). Ryser et al. clearly anticipates claims 22-24, 26 and 27, see the abstract.

Claims 22-27 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Williams et al. (WO 94/193321).

The claims are drawn to a composition comprising an inactivated HIV that has been inactivated with aldrithiol-2. Aldrithiol-2 has a CAS registry number 2127-03-9. Williams et al. teaches HIV inactivated by Bis (4-chlorophenyl) disulfide 2127-03-9, see the HCAPLUS search provided.

Claims 22-24, 26, and 27 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Levine et al. WO 93/15730.

Art Unit: 1648

The claims are drawn to a composition comprising an inactivated HIV that has been inactivated with 5,5'-dithiobis(2-nitrobenzoic acid). Levine et al. clearly anticipates claims 22-24, 26 and 27, see the abstract.

Claims 22, 26, and 27 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rice et al. (Nature. Feb., 1993, 361: 473-475).

The claims are drawn to a composition comprising inactivated HIV that has been activated by any derivative of a nitric oxide-containing compound. Rice et al. teaches inactivation of HIV-1 with a C-nitroso compound. Since no support for the negative limitation in claim 22 can be found in the original specification, and the C-nitroso compound would be a derivative of nitric oxide, Rice et al. clearly anticipates claims 22, 26, and 27.

Claims 22, 26, and 27 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Levine et al. (WO 92/15329).

The claims are drawn to a composition comprising inactivated HIV that has been activated by any compound containing copper. Levine et al. teaches a method for inactivating HIV with a copper compound that inactivates protease, see the abstract and the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 7:30-4:30 M-F.

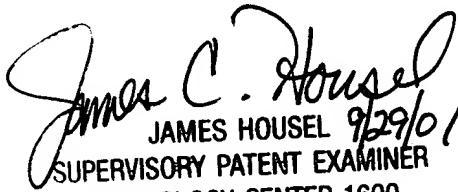
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the

Art Unit: 1648

organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley/SAF
September 24, 2001


JAMES HOUSEL 9/29/01
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600